UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

JONATHAN A. BLOOM, Plaintiff, v. SYLVIA M. BURWELL, Secretary of the U.S. Department of Health and Human Services, Defendant.	)	Civil Action No. 5:16-cv-121

DEFENDANT'S MOTION FOR REMAND PURSUANT TO THE SIXTH SENTENCE OF 42 U.S.C. § 405(g) AND MEMORANDUM OF LAW

Defendant, the Secretary of the U.S. Department of Health and Human Services ("the Secretary"), hereby requests that the Court issue an order remanding this case for further administrative proceedings pursuant to the sixth sentence of 42 U.S.C. § 405(g), as made applicable to this action by the Medicare Act at 42 U.S.C. § 1395ff(b)(1)(A).[1] In support of this motion, the Secretary submits the following memorandum of law.

I. INTRODUCTION

Plaintiff, Jonathan Bloom, brings this action pursuant to the Social Security Act, 42 U.S.C. § 405(g), and the Medicare Act, 42 U.S.C. § 1395ff(b)(1)(A),[2] to challenge a decision by the Medicare Appeals Council ("MAC" or "Council") denying Plaintiff's request for Medicare

[1] As required by Local Rule 7(a)((7), the Secretary has made a good faith attempt to obtain Plaintiff's agreement for the relief requested herein, but Plaintiff was unwilling to agree and intends to oppose this motion.

[2] In his Complaint, Plaintiff also alleges that jurisdiction is conferred by 28 U.S.C. § 1331. Complaint. ¶ 14. However, "§ 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." *Heckler v. Ringer*, 466 U.S. 602, 614-15 (1984) (quoting *Weinberger v. Salfi*, 422 U.S. 749 (1975)). *See also* 42 U.S.C. § 405(h) ("No action against the United States, or the [Secretary], . . . shall be brought under section 1331 . . . of title 28 to recover on any claim arising under this subchapter.").

coverage of a transmitter and disposable sensors for a continuous glucose monitor ("CGM") system. The MAC's decision is the final decision of the Secretary.

The MAC based its decision on the determination of the Medicare contractor for Plaintiff's jurisdiction, NHIC, Corp. ("NHIC"), that a CGM system does not fall into the Medicare benefit category for durable medical equipment ("DME")—and therefore, is not entitled to Medicare coverage—because it is "precautionary." *See* Exhibit A, Decision of Medicare Appeals Counsel, Docket No. M-15-4332, dated February 24, 2016, pp. 7-9. For items and services to be covered by Medicare, they must, in addition to other criteria, be eligible for coverage under a defined benefit category. *See* 42 U.S.C. §§ 1395k (scope of benefits under Medicare Part B) and 1395x (definition of medical and other health services). The MAC also took judicial notice of the website for Plaintiff's CGM manufacturer and supplier, Medtronic, as support for the determination that a CGM does not qualify as DME based on the functionality of the device. Exhibit A, pp. 7, 9.

Two reasons demonstrate good cause for remand of this case for further administrative proceedings. First, NHIC's determination that a CGM system does not fall into the Medicare benefit category for DME is contained in a Policy Article, and not in a local coverage determination ("LCD") expressly entitled to substantial deference pursuant to 42 C.F.R. § 405.1062(a). *See Finigan v. Burwell*, C.A. No. 15-12246-WGY, 2016 WL 2930905, at *5-6 (D. Mass. May 19, 2016); *Whitcomb v. Burwell*, C.A. No. 13-CV-990, 2015 WL 3397697, at *4 (E.D. Wis. May 26, 2015). However, the MAC appears to have misapplied the Policy Article as an LCD. *See* Exhibit A, p. 7; *see also* Complaint. ¶¶ 55, 129. Second, aside from the MAC's reliance on the Medtronic website, the administrative record does not contain substantive evidence regarding why a CGM system is considered precautionary and/or is otherwise outside of the Medicare benefit category for DME. *See Finigan*, 2016 WL 2930905, at *4 ("[I]n

asserting that the hearing officer's justification for 'depart[ing] from [the Policy Article]' was 'insufficient[,]' the Council did not explain what more would have rendered the record sufficient, or if, for example, a different type of evidence ought to have been proffered by [the plaintiff]." (quoted alterations in original) (internal citations omitted)).

Therefore, the Secretary recognizes that portions of the MAC's decision may have involved a misapplication of 42 C.F.R. § 1062(a) (substantial deference), *see Finigan*, 2016 WL 2930905, at *5, or otherwise are not well supported by the record below. Given this, as well as the decision of the District of Massachusetts in the substantially similar case *Finigan v. Burwell*, 2016 WL 2930905, good cause exists for a remand prior to answer. Accordingly, the Secretary respectfully requests that the Court remand this case pursuant to the sixth sentence of 42 U.S.C. § 405(g).[3] A remand will permit the MAC to reopen its decision to address any deficiencies in its decision and in the administrative record, and promote principles of judicial economy. Moreover, a remand at this early stage of the litigation is likely to result in a swifter decision on the merits. *See, e.g.*, 42 C.F.R. § 405.1140 (explaining that "when a case is remanded by a Federal district court for further consideration and the MAC remands the case to an ALJ, a decision subsequently issued by the ALJ [will] become[] the final decision of the Secretary unless the MAC assumes jurisdiction").[4]

[3] Sentence-six remands may be ordered where the Secretary requests a remand before answering the complaint, or where new, material evidence is adduced that was for good cause not presented before the agency. *Shalala v. Schaefer*, 509 U.S. 292, 297 n.2 (1993).

[4] Although it is the Secretary's position that remand is the proper next step for this case, as stated below, this does not necessarily mean that the Secretary believes that the MAC's ultimate decision to deny coverage is incorrect. The Secretary does not necessarily believe that the determination contained in the Policy Article—that is, that a CGM system does not fall within the Medicare benefit category for DME—is incorrect. Should the Court deny the Secretary's motion for remand, the Secretary would file its Answer and the Administrative Record, as it currently exists, and proceed with usual procedure in this Court for filing cross-motions for judgment on the administrative record. *See, e.g.* Local Rule 9(a) (describing the analogous procedure and briefing process for cases challenging decisions of the Commissioner of the Social Security Administration pursuant to 42 U.S.C. § 405(g)). In these cases, "the claimant bears the burden of proving [his] entitlement to Medicare coverage." *Keefe on Behalf of Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995) (citing *Friedman v. Secretary of the Dep't of Health and Human Services.*, 819 F.2d 42, 45 (2d Cir. 1987)).

II. STATUTORY AND REGULATORY FRAMEWORK

A. The Medicare Program

Medicare is a federal health insurance program for the aged, the disabled, and persons suffering from end stage renal disease.[5] The Medicare program is administered by the Centers for Medicare & Medicaid Services ("CMS"), which has contracted with private entities known as Medicare administrative contractors (and previously known as Medicare intermediaries). *See* 42 U.S.C. § 1395u.[6]

For items and services to be covered by Medicare, they must be eligible for coverage under a defined benefit category, be reasonable and necessary for the diagnosis or treatment of an injury or illness, and meet all applicable statutory and regulatory requirements.[7] The Medicare statute provides coverage for broad categories of benefits, including durable medical equipment ("DME"). Pursuant to 42 U.S.C. § 1395x(s), the Medicare statute defines "medical and other health services" to include DME as a separate benefit for which payment is authorized. 42 U.S.C. § 1395x(s)(6).

While the Medicare statute provides a general definition of DME, *see* 42 U.S.C. § 1395x(n), CMS has established criteria through the regulations at 42 C.F.R. § 414.202.[8] CMS

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[5] The Medicare program is composed of four parts: Part A (Hospital Insurance Benefits), 42 U.S.C. §§ 1395c–1395i-4; Part B (Supplemental Medical Insurance Benefits), 42 U.S.C. §§ 1395j–1395w-4; Part C (Medicare Advantage), 42 U.S.C. §§ 1395w-21–1395w-28; and Part D (Prescription Drugs), 42 U.S.C. § 1395w-101–1394w-153.

[6] Medicare contractors' responsibilities include making Medicare coverage determinations, paying for items and services provided to Medicare beneficiaries, auditing claims, and adjusting incorrect payments. *See* 42 U.S.C. § 1395kk-1(a)(4); 42 C.F.R. §§ 421.200, 421.400 *et seq*.

[7] 42 U.S.C. §§ 1395k (scope of benefits under Medicare Part B), 1395x (definition of medical and other health services), 1395y(a)(1)(A) and (B) (reasonable and necessary); *see also* Medicare Program; Notice of Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55, 634, 55,635 (Sept. 26, 2003) (describing general principles of Medicare coverage and payment, including these requirements). While this Federal Register notice was later superseded, *see* 78 Fed. Reg. 48,164 (Aug. 7, 2013) (Medicare Program; Notice of Revised Process for Making National Coverage Determinations), this subsequent notice did not alter the requirements for Medicare coverage, including that an item or service must fit within a Medicare benefit category.

[8] *See* Medicare Program; Final Rule on Durable Medical Equipment, 76 Fed. Reg. 70,228, 70,286 (Nov. 10, 2011) (discussing the history of the DME benefit and regulatory criteria for DME). Under those regulations, DME is

has provided guidance on these regulatory criteria through its *Medicare Benefit Policy Manual* ("MBPM").Exhibit A, pp. 5, 7-8. The MBPM defines DME consistent with 42 C.F.R. § 414.202. Exhibit A, pp. 7-8. In elaborating on equipment which is primarily and customarily used for medical purposes, the MBPM states that "first-aid or precautionary-type equipment (such as preset portable oxygen units) . . . are considered nonmedical in nature" and, therefore, "are not considered covered DME." MBPM, Ch. 15, § 110.1-B-2. *See* Exhibit A, p. 10 (discussing a similar provision in National Coverage Determination 280.1).

While many coverage determinations are made on a case-by-case basis, Congress has authorized the Secretary to issue binding National Coverage Determinations ("NCDs") regarding items or services. NCDs are binding on the contractors that process claims, on Administrative Law Judges ("ALJs") reviewing beneficiary claims, and on the MAC. 42 C.F.R. § 405.1060(a)(4). *See* 42 U.S.C. § 1395y(l); 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. § 400.202.[9]

The Medicare statute also authorizes individual Medicare contractors to issue Local Coverage Determinations ("LCDs") that identify circumstances in which particular items or services will or will not be covered within the jurisdiction of a specific contractor. 42 U.S.C. § 1395ff(f)(2)(B); 42 C.F.R. § 400.202.[10] Where there is no applicable NCD, Medicare

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specifically defined as . . . [E]quipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.
(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
(3) Is primarily and customarily used to serve a medical purpose.
(4) Generally is not useful to an individual in the absence of an illness or injury.
(5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

[10] More specifically, LCDs "specify under what clinical circumstances a service is considered to be reasonable and necessary," and are developed after "consider[ation of] medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community." *Medicare Program Integrity Manual* ("MPIM"), CMS Pub. No. 100-08, Ch. 13, § 13.1.3 (effective Jan. 1, 2012), http://www.cms.gov/ Regulations-and-Guidance/Guidance/Manuals/Downloads/ pim83c13.pdf.

contractors must still apply the "reasonable and necessary" limitation of 42 U.S.C. § 1395y(a)(1)(A) to determine whether a claim should be covered. *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004). Thus, "[t]he Secretary requires Medicare contractors to use LCDs to aid in this determination . . . ." *Id.*, and a contractor may deny certain claims if it has a "clear policy" that serves as the basis for denial. MPIM, Ch. 13, § 13.3. A contractor may also issue "Policy Articles" to guide Medicare coverage decisions, but these are not expressly entitled to "substantial deference" under the Medicare regulations.[11] 42 C.F.R. § 405.1062(a).

Standard home blood glucose monitors allow individuals to measure their blood glucose and, then, alter their diets or insulin dosages to ensure that they are maintaining an adequate blood glucose level.[12] During the time period relevant to this matter, NHIC, the DME contractor for Vermont, had issued LCD L11530 and Policy Article A33614, which further addressed coverage for certain types of blood glucose monitors.[13]

LCD L11530 focuses on metered, home blood glucose monitors that require a beneficiary to place a blood sample on a reagent strip before placing it into the monitoring device which

[11] Until the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. 106-554, contractor Local Medical Review Policies ("LMRPs") contained the information now found in LCDs. *See* Medicare Program; Final Rule, Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63,692 (Nov. 7, 2003). LMRPs often also included information such as coding provisions, benefit category provisions, statutory exclusion provisions, and payment prohibitions. 68 Fed. Reg. at 63,693. BIPA "amend[ed] section 1869(f)(2)(B) of the Act [42 U.S.C. § 1395ff(f)(2)(B)] . . . to define [an] LCD as 'a determination by a fiscal intermediary or carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on a [contractor]-wide basis . . ., in accordance with section 1862(a)(1)(A) ["reasonable and necessary," 42 U.S.C. § 1395y(a)(1)(A)].'" 68 Fed. Reg. at 63,693. Today, the information not related to Section 1862(a)(1)(A) previously found in an LMRP, such as benefit category, may be included in contractor "Policy Articles" related to an LCD. *See* MPIM, Ch. 13, § 13.1.3; Local Coverage Determination, CMS.GOV, http://www.cms.gov/medicare/coverage/ determinationprocess/lcds.html (last visited Feb. 15, 2016); *see also Finigan*, 2016 WL 2930905, at *5-6.

[12] Coverage for home blood glucose monitors (also known as glucometers) is discussed in NCD 40.2, Home Blood Glucose Monitors. *See* Medicare Coverage Database, CMS.GOV, https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx; *see also* Medicare Program; Special Payment Limits for Home Blood Glucose Monitors, 60 Fed. Reg. 3405 (Jan. 17, 1995).

[13] Full copies of these documents are available online through the Medicare Coverage Database Archive site, located at http://localcoverage.cms.gov/mcd_archive/overview.aspx. Both LCD L11530 and Policy Article A33614 were retired subsequent to Plaintiff's requests for coverage. The newest version of both documents are substantially similar to their prior versions. *See In re: Local Coverage Determination Complaint: Glucose Monitors*, HHS Departmental Appeals Board ("DAB") ALJ Decision No. CR4596, 2016 WL 2851236, 1 n.1 (Apr. 29, 2016).

processes and reads the strip. *See* Exhibit A, p. 9. LCD L11530 does not specifically address coverage for CGM systems. *See* Exhibit A, pp. 9-10. However, Policy Article A33614 contains additional Medicare coverage information for glucose monitors, including CGMs. Exhibit A pp. 9-10. Policy Article A33614 specifically explains that "'[CGMs] . . . are considered precautionary and therefore non-covered under the DME benefit.'" Exhibit A.

B. The Medicare Appeals Process And Sentence Six Remands

The Medicare statute provides beneficiaries with two separate appeals processes for challenging determinations of the Secretary. First, the statute provides that a beneficiary may appeal from the denial of a claim for Medicare benefits (the "claims appeal process"). *See* 42 U.S.C. § 1395ff(b). Second, the statute provides a separate process for challenging NCDs and LCDs (the "LCD review process"). *See* 42 U.S.C. § 1395ff(f); 42 C.F.R. § 426.310(a) (specifically stating that "LCD and NCD reviews are distinct from the claims appeal processes"). However, the regulations do permit an individual beneficiary to pursue both appeal processes simultaneously. *See* 68 Fed. Reg. at 63,694. [14]

Under the claims appeal process, beneficiaries may appeal the denial of their benefit claim through three levels of administrative review. *See* 42 C.F.R. Part 405, Subpart I. In rendering their decisions, the ALJ and the MAC "are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). Once all levels of agency review are completed and the Secretary issues a final decision, judicial review of the administrative decision is authorized by 42 U.S.C. § 405(g). [15]

[14] Here, Plaintiff pursued his administrative challenge to the denial of Medicare coverage solely under the claims appeal process, as opposed to the LCD review process.

[15] This provision applies to disputes regarding claims for payment under the Social Security Act and is applicable to disputes for Medicare claims, except that in such cases, references to the Commissioner should be considered references to the Secretary. *See* 42 U.S.C. § 1395ff(b)(1).

This statutory framework is the exclusive authority for review of such claims. *See Heckler v. Ringer*, 466 U.S. 602, 605 (1984); *Abbey v. Sullivan*, 978 F.2d 37, 43 (2d Cir. 1992). The sixth sentence of 42 U.S.C. § 405(g) provides, in relevant part, that "the court may, on motion of the [Secretary] made for good cause shown before the [Secretary] files [her] answer, remand the case to the [Secretary] for further action by the [Secretary][.]" 42 U.S.C. § 405(g). Consequently, this language "permits the district court to remand without making any substantive ruling as to the correctness of the [Secretary's] decision . . . ." *Raitport v. Callahan*, 183 F.3d 101, 104 (2d Cir. 1999). *See also Schaefer*, 509 U.S. at 297 n.2 (1993). The Secretary must submit her request for a remand prior to filing her Answer, and that request must be predicated on "good cause." 42 U.S.C. § 405(g). *See Schaefer*, 509 U.S. at 297 n.2; *see also Raitport v. Callahan*, 183 F.3d 101, 104 (2d Cir. 1999).

In determining whether good cause for the Secretary's request exists, "due deference" should be given to the Secretary's judgment. *Doctors Nursing & Rehab. Ctr. v. Sebelius*, 613 F.3d 672, 681 (7th Cir. 2010). Courts, including the Supreme Court, have found good cause where the decision being challenged contains a legal error, or where the administrative record is unclear. *Cf. Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("If the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course . . . is to remand to the agency for additional investigation or explanation."); *see also Art of Healing Medicine, P.C. v. Burwell*, 91 F. Supp.3d 400, 417 (E.D.N.Y. 2015) ("The Secretary's admission of error constitutes 'good cause' for a sentence six remand."); *Torres v. Shalala*, 938 F. Supp. 211, 217 (S.D.N.Y. 1996) ("Here, the Secretary has moved to remand prior to filing an answer and has demonstrated good cause by acknowledging legal error."); *Botta v. Barnhart*, 475 F. Supp.2d 174, 186 (E.D.N.Y. 2007)

(explaining that "[r]emand . . . for further administrative procedures is an appropriate remedy where . . . 'there are gaps in the administrative record'" (quoting *Rosa v. Callahan*, 168 F.3d 72, 82-83 (2d Cir. 1999) or where "new, material evidence is adduced that was not produced before the agency" (citing *Raiport*, 183 F.3d at 104)).

Where the Secretary has established good cause, "the weighty interest of an agency in correcting its own mistakes will generally prevail in the absence of concerns of strategic behavior or gross inefficiency." *Doctors Nursing & Rehab. Ctr.*, 613 F.3d at 681. A remand pursuant to sentence six is "the proper course" in such cases. *Fla. Power & Light Co.*, 470 U.S. at 744.

III. STATEMENT OF FACTS AND PRIOR ADMINISTRATIVE PROCEEDINGS

Plaintiff, Jonathan Bloom, is a Medicare beneficiary with type 1 diabetes. Exhibit A, p. 4. Plaintiff has used a continuous glucose monitor ("CGM") system since 2006. *Id.* Plaintiff testified before an ALJ that a CGM is comprised of multiple parts, including a disposable sensor "put in with a needle" "and a transmitter [that] is hooked up to the sensor." According to Plaintiff, the disposable sensors last for six days. Plaintiff's particular system also has an insulin pump. However, even when using a CGM, a patient still must monitor blood glucose levels via traditional finger stick monitoring. Exhibit A, p. 10.

Plaintiff's requests for Medicare coverage for disposable sensors furnished to him in March 2014 and in June 2014, and for a CGM transmitter furnished to him on June 27, 2014 were denied at all levels of the administrative appeals process. Exhibit A, pp. 4-7. In a decision dated February 24, 2016, the MAC upheld the denial of Plaintiff's requests for coverage. The MAC found, first, that there was no applicable National Coverage Determination to Plaintiff's request, Exhibit A, pp. 8-9, and thus asked "whether the contractor ha[d] issued a relevant LCD and/or related policy article that was in effect on the date of service at issue." *Id.* at 9. With

regard to Plaintiff's requests for coverage, the MAC found that "the contractor . . . had published LCD L11530 and related Policy Article A33614, both entitled 'Glucose Monitors.'" Exhibit A, p. 9. In particular, the MAC found that the LCD contained language that pointed to "[t]he Non-Medical Necessity Coverage and Payment Rules section of the Related Policy Article[,] [which] contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified." Exhibit A, p. 10 (emphasis removed). Looking to Policy Article A33614, the MAC found that the Policy Article "makes clear that [Plaintiff's] CGM items do not meet the definition of DME because they are precautionary." Exhibit A, p. 10. The MAC noted that it has "[h]istorically given substantial deference to policy articles." Exhibit A, p. 9.

In addition, the MAC sought to provide an explanation of the Policy Article's position on CGMs. Regarding the term "precautionary," the MAC stated:

> While the term 'precautionary' is not a statutorily defined term, it refers to the requirement that DME must itself serve a medical purpose. Where the beneficiary must still use another device to accomplish the medical purpose at issue, it is essentially used as an additional precaution, but not for a primary medical purpose.

Exhibit A, p. 10 (emphasis in original). The MAC then considered Plaintiff's hearing testimony and took judicial notice of the website for Medtronic, the manufacturer and supplier of Plaintiff's CGM system. Exhibit A, pp. 10-11. In doing so, the MAC determined that traditional blood glucose monitoring (i.e., monitoring achieved via finger stick) is still required for individuals using a CGM—"to calibrate the CGM," and "'to check blood glucose levels . . . before therapy adjustment." Exhibit A, p. 11 (citing the manufacturer's website). Thus, the MAC concluded that "the CGM does not substitute for the existing means of controlling insulin usage, or measure

blood glucose directly[16], . . . [but] merely provides an added precaution and does not itself serve a primary medical purpose." Exhibit A, p. 11. And for this reason, the MAC found "no basis to depart from the applicable program guidance . . . ." *Id.*

IV. ARGUMENT

In light of portions of the decision issued by the Medicare Appeals Council in this case, the current administrative record, and the recent decision of the District of Massachusetts in *Finigan v. Burwell*, there is good cause for remanding this matter pursuant to the sixth sentence of 42 U.S.C. § 405(g). Given that the Secretary has not yet filed her Answer, this motion is timely, and the Court should thus remand this case to the Secretary for further administrative proceedings. And indeed, remand would provide the Secretary an opportunity to address the concerns about the administrative proceedings voiced by Plaintiff in his Complaint.[17]

Good cause is present in the MAC's treatment of Policy Article A33614. In its decision, the MAC outlined its task under the Medicare statutes and regulations, and assessed whether there was an applicable NCD . *See* Exhibit A, pp. 7-8. The MAC found no applicable NCD, and pointed to LCD L11530 and Policy Article A33614. Regarding these types of documents generally, the MAC explained:

> "An LCD is a decision by a Medicare administrative contractor . . . whether to cover a particular item or service on a [contractor]-wide basis in accordance with Section 1862(a)(1)(A) of the [Act] (i.e., a determination as to whether the item or service is reasonable and necessary)." Information that is not related to reasonableness and necessity coverage criteria is published through an article. The Council, like the ALJ, is not bound by program guidance, including specifically "LCDs, LMRPs, or . . . program memoranda and manual

[16] Earlier in its decision, the MAC references the manufacturer's website for information regarding the functionality of a CGM, including that a CGM "measure[s] glucose levels in tissue fluid." Exhibit A, p. 9.

[17] To the extent Plaintiff may be concerned about review of his benefit claim being prolonged, the Secretary notes that a remand (which has been the ultimate result in similar, recently litigated cases) at this stage of the litigation would likely result in a swifter decision, and a return to this Court for either entry of judgment or litigation on the merits if the Plaintiff remains unsatisfied with the agency's decision after remand. *See, e.g.*, 42 C.F.R. § 405.1140. The Secretary would not object to providing status updates to this Court on the progress of Plaintiff's case.

> instructions," but we must give these policies substantial deference if they are applicable in a given case. If an ALJ or the Council declines to follow this guidance, the decision must explain the basis for his departure. Historically, we have also given substantial deference to policy articles.

Exhibit A, p. 9 (internal citations omitted) (alterations in original). The MAC then focused on Policy Article A33614's statement regarding Medicare coverage for CGMs—that is, the contractor's determination that "'[CGMs] . . . are considered precautionary and non-covered under the DME benefit.'" Exhibit A, p. 10. The MAC found the statement to be "of particular importance in this case," and aligned with the language in affirming the denial of Plaintiff's requests for coverage. Exhibit A, p. 10-12.

Although the MAC did not expressly state that it was affording substantial deference to Policy Article A33614 in this instance, it appears the MAC may have done so. The MAC pointed to limited evidence, *see* Exhibit A, p. 10-11 (citing Plaintiff's hearing testimony and excerpts from the Medtronic website[18]), prior to reaching the same conclusion as the Policy Article that "CGMs . . . do not meet the definition of DME because they are precautionary." Exhibit A, p. 11. *Accord Finigan*, 2016 WL 2930906, at *4 ("The only evidence to which the Council pointed . . . was the safety label on [the plaintiff's] CGM[] . . .."), *6 ("The Council's decision that 'the record is insufficient to depart from the [Policy Article]' . . . thus incorporates a false premise: that this Policy Article, like a Local Coverage Determination, was entitled to 'substantial deference' . . . .").

The Secretary recognizes that, as other district courts have found, a Policy Article should not be misapplied as an LCD. *See* 42 C.F.R. § 405.1062(a); *Finigan*, 2016 WL 2930906, at *6; *see also Finigan*, 2016 WL 2930906, at *5 ("While vacating the Secretary's decision because of the difference between a 'Policy Article' and a 'Local Coverage Determination' might sound like

[18] Neither ALJ decision before the Council referenced the manufacturer's website.

the height of legalistic formalism, this difference is a meaningful one."); *Whitcomb*, 2015 WL 3397697, at *4 (explaining that "[l]ooking to Articles for coverage determinations would undermine Section 522 of BIPA, whereby Congress created the right for certain beneficiaries to challenge coverage language contained in LCDs."); Complaint ¶¶ 128-132 (asserting that the MAC granted improper deference to the Policy Article). Given that concern here, there is good cause for remanding the case to the Secretary to ensure the determination on Plaintiff's benefit claim accords with the applicable statutes and regulations. *See, e.g.*, *Roderick L. Bremby, Commissioner v. Burwell*, No. 3:15-cv-1397 (D. Conn. Apr. 29, 2016); *Art of Healing Med.*, 91 F. Supp.3d at 417; *Torres*, 938 F. Supp. at 217.

Good cause for a sentence six remand further exists because the administrative record lacks evidence pertaining to the functionality of a CGM system and whether it qualifies as DME. *See Fla. Power & Light Co.*, 470 U.S. at 744 ("If the record before the agency does not support the agency action, . . . or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course . . . is to remand to the agency for additional investigation or explanation."); *Finigan*, 2016 WL 2930905, at *5, *7 (remanding for further record development on whether a CGM system is DME); *see also* Complaint ¶¶ 105-108 (asserting that the MAC rendered its decision "[w]ithout support"). The MAC looked to two sources for evidence regarding the "precautionary" nature of CGMs. *See* Exhibit A, pp. 10-11. However, the administrative record as a whole lacks substantive information concerning the functionality of a CGM, including its functionality in conjunction with or in comparison to a traditional blood glucose monitor. *Finigan*, 2016 WL 293095, at *6 n.6 (recognizing a similar gap in the administrative record). Consequently, even if the Policy Article's determination that "'[CGMs] . . . are considered precautionary and therefore non-covered under the DME benefit,'" Exhibit A, p. 10, is correct, the conclusions reached by the MAC and ALJs about the

appropriateness of that determination are largely unsupported by the record. Remand to the Secretary is "the proper course" in this instance. *Fla. Power & Light Co.*, 470 U.S. at 744.

In addition, there is good cause for a remand because a remand would promote principles of judicial economy and efficiency. *See, e.g.*, *Ethyl Corp. v. Browner*, 989 F.2d 522, 523-24 (D.C. Cir. 1993) (noting that remand promotes judicial economy by allowing agency to reconsider and rectify erroneous decision without further expending judicial resources); *Frito-Lay, Inc. v. Dep't of* Labor, 20 F. Supp.3d 548, 554-56 (N.D. Tex. 2014) (discussing remand, and explaining that "courts often rely on the principle of judicial economy, deciding to preserve the court's scarce judicial resources by providing the federal defendants the opportunity to cure their own mistakes"); *see also Reyes v. Rite-Line Transp., Inc.*, No. 13-Civ. 968, 2013 WL 3388975, at *4 (S.D.N.Y. Jul. 8, 2013) (finding remand "especially appropriate . . . considering the real risk of inconsistent verdicts" and judicial economy). On remand, the MAC will have the opportunity to meaningfully consider (including how to best address) the issues described above, which mirror multiple arguments Plaintiff has raised in his Complaint. *See, e.g.*, Complaint ¶¶ 44, 55, 96, 105-108, 128-132. The MAC, the entity within HHS devoted to understanding the intricacies of the Medicare program as it relates to coverage for Medicare beneficiaries, is in the best position to assess and remedy these concerns. Nonetheless, in the event Plaintiff remains dissatisfied following remand, this Court will then have a fuller decision and record to review; the sixth sentence of 42 U.S.C. § 405(g) provides that after a remand, the Secretary must "file with the [C]ourt any such additional and modified findings of fact and decision, and, in any case . . . not . . . fully favorable to the individual, a transcript of the additional record and testimony upon which the [Secretary's] action in modifying or affirming was based." 42 U.S.C. § 405(g).

As a final matter, a remand in this case would align with the decisions issued by the other district courts that have recently addressed Medicare coverage for CGM systems, as well as

result in a swifter adjudication on Plaintiff's benefit claim while being consistent with those cases. *See Finigan v. Burwell*, C.A. No. 15-12246-WGY, 2016 WL 2930905 (D. Mass. May 19, 2016) (remanding case to the Secretary based on MAC's deferential treatment of Policy Article A33614, and for "a determination of whether the [CGM system] qualifies as 'durable medical equipment' under the regulations"); *Whitcomb v. Burwell*, C.A. No. 13-CV-990, 2015 WL 3397697 (E.D. Wis. May 26, 2015) (remanding case "to permit the Secretary to assess th[e] case under the proper legal standard"); *see also* 42 C.F.R. § 405.1140. Furthermore, as noted previously, the Secretary would not object to providing status updates to this Court on the progress of Plaintiff's case during the remand process.

V. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court remand this case pursuant to the sixth sentence of 42 U.S.C. § 405(g) for further administrative proceedings.

Dated at Burlington, in the District of Vermont this 10th day of August, 2016.

Respectfully submitted,

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